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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/086,745 | 02/28/2002 | Gary de Jong | 24601-416C | 8781 |

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| EXAMINER | |
|---|---|
| LAMBERTSON, DAVID A | |
| **ART UNIT** | **PAPER NUMBER** |
| 1636 | |

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Advisory Action | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/086,745 | DE JONG ET AL. | |
| | Examiner | Art Unit | |
| | David A. Lambertson | 1636 | |

*--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED 29 October 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *18-22,40 and 41*.

   Claim(s) objected to: *35-39*.

   Claim(s) rejected: *17,31 and 33*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

JAMES KETTER
PRIMARY EXAMINER

Continuation of 5. does NOT place the application in condition for allowance because: Applicant's arguments are not persuasive to overcome the rejection under 35 USC § 102(b) in view of Nolan et al. Applicant contends that the teachings of Nolan indicate that the labeling of the artificial chromosome occurs after the delivery of the artificial chromosome into the cell, whereas the instant method requires that the "large nucleic acid" be labeled prior to delivery. Applicant suggests that the following paragraph (page 9, line 25 to pag 10, line 6) clearly indicates that the method of Nolan does not teach labeling the artificial chromosome prior to delivery:

"There are numerous means for determining the successful incorporation of a single chromosome into the cell. It is presently preferred that the verification be made by a FACS machine. Presently, it is preferred that the chromosome be fluorescently labeled. Thus, after insertion of the chromosome, the cell can pass into a recovery chamber where its fluorescent scatter properties are analyzed by the FACS to determine whether one and only one chromosome has been inserted. Current artificial chromosomes are very AT rich due to the fact that they contain a large percentage of pericentric alpha satellite DNA, which is very AT rich. This type of chromosome is identified and sorted by using chromomycin A3 and Hoechst 33258 stains and dual laser high speed now cytometry. The AT rich chromosomes carry a specific ratio of the dyes and can be identified in this manner."

The third sentence clearly indicates that "it is preferred that the chromosome be fluorescently labeled" in reference to the incorporation of a single chromosome into a cell. Nothing in this sentence indicates that the chromosome must or is labeled after its introduction into the host cell, thus there is no reason to conclude this as a fact. Thus, Nolan contemplates using a fluorescently labeled chromosome in their method. Nowhere in the citation made by Applicant does Nolan teach that the labeling of the artificial chromosome must occur, or even does occur, after the delivery of the chromosome into the cell.

Furthermore, it is noted that Applicant does not define what a "label" is in the instant specification. Thus, the skilled artisan would interpret "label" to have its common meaning, which is "To identify or designate with a label." Thus, even if Nolan did teach using chromomycin A3 and Hoechst 33258 stains as the only means of "fluorescently" labeling the artifiicial chromosome, and only taught using said labels after incorporation of the chromosome into the host cell, this does not preclude Nolan from serving as an anticipatory reference. This is because the chromosomes used by Nolan are artificial, therefore they are synthesized as containing AT-rich segments. These segments meet the common meaning of "labeled" because they can be detected, e.g., using chromomycin A3 and Hoechst 33258. Thus, Nolan teaches using a "labeled" large nucleic acid in their method, using the commonly accepted meaning of the term "label." It is noted that nothing in Applicant's claim or specification necessitates that the label be detected directly, thus nothing precludes an AT-rich segment from meeting the limitations of being a "label."